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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/479,145	Weinstein
Examiner	**Group Art Unit**
Robert C. Hayes	1647

Responsive to communication(s) filed on _____.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *1-32* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

X Claims *1-32* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 4-6, 14-15, 17, 19-20, 22, 24 & 28, drawn to polynucleotides encoding a murine Opa1 polypeptide, vectors, associated host cells, and method of producing the murine Opa1 protein, classified in Class 435, subclass 69.4.

II. Claims 1, 3, 4-5, 7, 14, 16, 18, 19, 21, 23-24 & 28, drawn to polynucleotides encoding a human Opa1 polypeptide, vectors, associated host cells, and method of producing the human Opa1 protein, classified in Class 435, subclass 69.4.

III. Claims 8-10, 12 & 29, drawn to murine Opa1 polypeptides, and compositions of such, classified in Class 530, subclass 399.

IV. Claims 8-9, 11, 13 & 29, drawn to human Opa1 polypeptides, and compositions of such, classified in Class 530, subclass 399.

V. Claim 25, drawn to a method of inducing growth or regeneration of nervous tissue comprising administrating Opa1 polypeptides, classified in Class 514, subclass 2.

VI. Claims 26-27 & 31, drawn to gene and cell therapy methods of inducing growth or regeneration of nervous tissue comprising administration of nucleic acids or genetically modified cells encoding Opa1 polypeptides, classified in Class 514, [illegible] or Class 424, subclass 93.21, respectively.

VII. Claim 30, drawn to a method of inducing growth or regeneration of nervous tissue comprising administrating a modulator of Opa1 expression, classified in Class/subclass varies.

VIII. Claim 31, drawn to method of evaluating whether an agent induces growth or regeneration of nervous tissue by effecting Opa1 expression, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products; restriction is deemed proper because these products appear to constitute patently distinct inventions for the following reason:

Groups I-IV are directed to products that are physically and functionally distinct, which involve distinct polynucleotides and polypeptides from different species. Each of these products can also be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/purification procedures. It is noted that the polynucleotides of Groups I & II and the polypeptides of Groups III & IV are directed to structurally distinct Opa1 molecules. In addition, the polypeptides of Groups III & IV are [illegible] than the nucleic acid molecules of Groups I & II, which in turn

Further, the proteins of Groups III & IV do not require the vectors and host cells of Groups I-II, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Groups III-IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of Groups III-IV can be used in other materially different methods, such as in affinity chromatography to isolate co-factors or receptor molecules, or to used to generate antibodies. The methods of inducing growth or regeneration of nervous tissue require nervous tissue and patients with neurodegenerative disease states, as well as appropriate administration protocols, which are not required for the products of Groups III-IV. Therefore, these groups are distinct and separable for the reasons stated.

It is noted that the methods of Group V does not require the products of Groups I-II, and vice versa.

Inventions I-II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown as stated above (M.P.E.P. § 806.05 h)). In the instant case, the nucleic acids of Groups I-II can be used to encode the full

and cell therapy methods for inducing growth or regeneration of nervous tissue require nervous tissue and patients with neurodegenerative disease states, as well as appropriate administration protocols, which are not required for the products of Groups I-II. Therefore, these groups are distinct and separable for the reasons stated.

Additionally, it is noted that the method of Group VI does not require the products of Groups III-IV, and vice versa.

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Groups V-VIII are directed to methods of inducing growth or regeneration of nervous tissue with either polypeptides, nucleic acids/cells expressing such, or with modulators of Opa1 expression, or directed toward methods of evaluating whether an unknown agent can induce growth or regeneration of nervous tissue. In other words, each of the methods require physically and functionally distinct elements. For example, the use of polypeptides in Group V to treat nervous tissue involves entirely different administration protocols than those required in the methods of Group VI using DNA or transfected cells, or those required for the method of Group VII using Opa1 modulators, and vice versa. In addition, the treatment methods of Groups V, VI [illegible] products which include polypeptides, nucleic acids, or unknown

growth or regeneration of nervous tissue of Group VIII is distinguished from the methods for treatment in Groups V-VII, in that the diagnostic method of Group VIII requires labeling protocols to detect Opa1 expression, unlike the treatment methods of Groups V-VII, which themselves may require patients, unlike the diagnostic method of Group VIII. Finally, the methods of Groups VI and VIII require modulators or agents capable of effecting Opa1 expression, unlike the treatment methods of Groups V or VII, which specifically require administering Opa1 polypeptides or nucleic acids themselves. These inventions are, therefore, patentably distinct, since one is not required for the other.

3. Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
March 6, 2001

PATRICIA A. DUFFY
PRIMARY EXAMINER